IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08-948 (LDD)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

BRIEF OF DEFENDANTS APOTEX INC. AND APOTEX CORP. IN SUPPORT OF THEIR MOTION TO TRANSFER VENUE OR, ALTERNATIVELY, TO STAY THESE PROCEEDINGS

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Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully submit this brief in support of their motion to transfer venue or, alternatively, to stay these proceedings.

I. INTRODUCTION

This is one of two ***identical*** actions filed by Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC (collectively, "Pfizer"), involving the exact same patent and the exact same parties. Pfizer's effort to proliferate proceedings and engage in forum and judge shopping should not be countenanced by this Court. For the following reasons, the Court should transfer this action to the United States District Court for the Northern District of Illinois, Eastern Division, or alternatively, stay this action pending resolution of that ***identical*** action.[1]

By way of background, Apotex Inc. filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic atorvastatin calcium drug product to compete with Pfizer's brand product, Lipitor®—a prescription drug used to lower cholesterol. To delay approval of Apotex Inc.'s competing generic drug, Pfizer filed ***identical*** actions for alleged patent infringement both here and in Illinois (*Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-07231 (N.D. Ill.)), alleging infringement of the now-surrendered U.S. Patent No. 5,273,995 ("the '995 patent"). (*See* D.I. 1, Complaint; Phillips Decl. Ex. A[2], NDIL Compl.). Apotex has answered and counterclaimed in Illinois, where the parties and the case are currently proceeding. (*See* Phillips Decl. Ex. B, NDIL Answer, Defenses, Countercl. and Jury Demand of Defs. Apotex Inc. and Apotex Corp. ("Apotex NDIL

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[1] Apotex Inc. has separately moved to dismiss for lack of personal jurisdiction, and Apotex Corp. has moved to dismiss for lack of an indispensable party.

[2] All references to "Phillips Decl." are to the Declaration of John C. Phillips, Jr., Esq., submitted concurrently herewith.

Answer")). Moreover, multiple motions are currently pending before the Illinois Court, including Pfizer's motion for leave to file its First Amended Complaint (Phillips Decl. Ex. R); Pfizer's motion to dismiss Apotex's counterclaims (Phillips Decl. Ex. N); and Apotex's Rule 12(b)(1) and (6) motion to dismiss (Phillips Decl. Ex. P). (*See also* Phillips Decl. Ex. X, NDIL action docket sheet at D.I. 46, 54, and 59).

In the interest of justice, and for the convenience of the Court and parties, the Court should transfer this action to Illinois. Pfizer has consented to suit in that District and, having voluntarily chosen to sue Apotex there, Pfizer certainly cannot legitimately complain about litigating in Illinois. Nor is Pfizer entitled to maintain duplicative actions against Apotex in separate Districts. Courts, including this District, have squarely rejected such tactics, making clear (for good reason) that Pfizer cannot game the system by filing identical actions in different courts and then picking the court in which it wishes to proceed. In addition to obvious concerns about forum- and judge-shopping, such identical suits waste the resources of the parties and this Court, and seriously risk inconsistent results—all of the things that transfer under 28 U.S.C. § 1404(a) is designed to prevent. The existence of the identical Illinois action is reason enough to transfer this case.

In the alternative, the Court should stay these proceedings pending resolution of Pfizer's identical action in Illinois. Absent dismissal of this suit or transfer, a stay is necessary to avoid the real risk of inconsistent results on the validity, infringement and enforceability of the patents-in-suit; to prevent the needless waste of judicial resources; and to eliminate substantial expense and prejudice to Apotex from having to litigate the same dispute twice.

II. NATURE AND STAGE OF THE PROCEEDINGS

This Hatch-Waxman patent case concerns the '995 patent and U.S. Patent No. RE 40,667 E ("the '667 patent"). Pfizer filed this action on December 17, 2008, along with an ***identical*** action the same day in Illinois. (*See* D.I. 1, Complaint; Phillips Decl. Ex. A, NDIL Compl.). Both complaints asserted infringement of only the '995 patent. (*Id.*) In response to the Complaint filed in this action, Apotex filed motions to dismiss and transfer (*See* D.I. 9; 11).

On March 17, 2009, the United States Patent and Trademark Office ("USPTO") reissued the '995 patent as the '667 patent. (D.I. 25 at Ex. B, the '667 patent cover page). On March 17, 2009, the date the '667 patent issued, Apotex filed a FED. R. CIV. P. 12(b)(1) and (6) Motion to Dismiss seeking dismissal of the Complaint because, upon issuance of the '667 patent, the '995 patent was necessarily surrendered to the USPTO and is no longer enforceable. *See* 35 U.S.C. §§ 251-252. (D.I. 22, Motion to Dismiss for Lack of Jurisdiction Over the Subject Matter and Failure to State a Claim). Further, Apotex Inc. amended its ANDA to include a paragraph IV certification stating that Pfizer's '667 patent is invalid and/or not infringed by Apotex Inc.'s ANDA product. Apotex Inc. also provided Pfizer with notice of its paragraph IV certification for the '667 patent, again identifying its agent for service of process in Illinois. (Phillips Decl. Ex. S). In response, Pfizer filed the First Amended Complaint in this action alleging infringement of the '667 patent, but also maintaining a claim of infringement for the '995 patent, a patent that no longer exists. (D.I. 25, First Am. Compl. ¶¶ 46-56). The First Amended Complaint also included new jurisdictional averments that had not been included in the original Complaint. (*Id.* ¶¶ 28, 34-40, 42, 44-45). Pursuant to a stipulated extension (D.I. 26, 27), Apotex Inc. and Apotex Corp. now bring this timely motion to transfer venue to Illinois or, alternatively, to stay proceedings pending resolution of the identical Illinois action.

III. SUMMARY OF ARGUMENT

For the reasons set forth in Apotex Inc.'s brief in support of its motion to dismiss for lack of personal jurisdiction, submitted concurrently herewith, this Court lacks personal jurisdiction over Apotex Inc., the ANDA applicant and only proper defendant, thus requiring dismissal. Likewise, the action against Apotex Corp.—which did not prepare or file the ANDA, is not the ANDA applicant and is not a proper defendant—must be dismissed as well for lack of an indispensable party. However, even if this Court were to deny or otherwise decline to reach that motion, this case does not belong here. It belongs in Illinois, where an ***identical*** action is already pending involving the same parties, patents and accused product. The parties there have consented to jurisdiction and venue and are at issue in Illinois. The powerful interests of justice in avoiding wasteful and duplicative litigation, along with the weak, if non-existent, connection to this forum, weigh decidedly in favor of transfer to Illinois; in the alternative, a stay of proceedings is in order to avoid the possibility of inconsistent results with the identical Illinois action.

IV. STATEMENT OF FACTS

This action and Pfizer's identical Illinois action arise under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.[3] Congress enacted Hatch-Waxman for the express purpose of "get[ting] generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve that goal, Hatch-Waxman created the ANDA procedure and "a mechanism to facilitate the adjudication of

[3] Hatch-Waxman is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271).

claims of infringement of patents relating to the innovator's drugs" *before* the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

A. Statutory and Regulatory Framework.

In order to obtain FDA approval to sell a drug that has not been previously approved, like Lipitor®, a company generally must file a new drug application ("NDA"). *See* 21 U.S.C. § 355(b)(1). In addition to safety and efficacy information, an NDA applicant must file with FDA the number and expiration date of any patent that claims "the drug" or a method of using "the drug" for which the applicant submitted the application. 21 U.S.C. §§ 355(b)(1), (c)(2). FDA publishes this information in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

A generic drug company may file an ANDA, as Apotex Inc. did here, for FDA approval to market a generic version of a previously-approved NDA drug. An ANDA is "abbreviated" in that it substitutes bioequivalence data for the full studies of safety and efficacy found in an NDA. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). An ANDA also generally must contain one of four "certifications" for each patent that the NDA applicant has submitted for listing in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). With certain exceptions not applicable here, an ANDA applicant seeking approval to market a generic drug before expiration of a listed patent must submit a "paragraph IV certification" stating that the listed patent is invalid and/or will not be infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA applicant must then notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B).

The submission of an ANDA with a paragraph IV certification constitutes a "technical" or "highly artificial" act of infringement that creates the subject matter jurisdiction necessary for a district court to resolve any disputes regarding patent infringement or validity before the generic drug is actually sold. *See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application under [21 U.S.C. § 355(j)] . . . if the purpose . . . is to obtain approval . . . before the expiration of such patent."); *Eli Lilly*, 496 U.S. at 678 (holding that 35 U.S.C. § 271(e)(2)(A) created "a highly artificial act of infringement that consists of submitting an ANDA" with a paragraph IV certification). The "very limited and technical purpose" of this "highly artificial act" is to permit suit to be brought despite the fact that generic companies have not yet infringed the patents at issue. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349, 1351 (Fed. Cir. 2004).

If the patent owner files such a suit within 45 days of receiving notice of the ANDA and paragraph IV certification, FDA approval of the ANDA is automatically stayed—regardless of the suit's merit or lack thereof—until the earlier of 30 months or a judicial determination that the patent is invalid and/or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The patent owner, like Pfizer here, therefore has every incentive to delay resolution of the action, and in turn, the approval of the competing generic drug for as long as possible.[4] In exchange for

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[4] In exchange for this powerful 30-month approval stay, Congress imposed an express statutory duty on all parties to "reasonably cooperate in expediting the action" and empowered the courts, *inter alia*, to shorten the 30-month stay if the brand company breaches this duty. 21 U.S.C. § 355(c)(3)(C) (emphasis added); *see also Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 40 (D.D.C. 2000) (explaining that the Hatch-Waxman drafters expected litigation to be concluded during this time). "Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires that, in these actions, 'each of the parties shall reasonably cooperate in expediting the action.'" *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 487 (E.D. Va. 2005) (quoting 21 U.S.C. § 355(c)(3)(C)).

this automatic 30-month stay of approval of the competing generic drug, Congress imposed an express statutory duty on all parties to "reasonably cooperate in expediting the action." *Id.* Congress also empowered the district court, among other things, to shorten the 30-month stay if the brand company breaches this duty. *See id.*

B. Pending Litigation.

Apotex Inc. submitted an ANDA for 10 mg, 20 mg, 40 mg, and 80 mg atorvastatin calcium tablets. (*See* Tao Decl. ¶ 15)[5]. Apotex Inc. prepared and compiled the ANDA in Canada, where Apotex Inc. is incorporated and located. (*See id.* ¶ 18). Apotex Inc.'s original ANDA contained a paragraph IV certification for four of the five Orange Book patents originally listed for Lipitor®: the '995 patent and U.S. Patent Nos. 5,686,104 ("the '104 patent"); 5,969,156 ("the '156 patent"); and 6,126,971 ("the '971 patent"). In addition, on March 18, 2009, Pfizer listed the '667 patent in the Orange Book for Lipitor®. Apotex Inc. amended its ANDA to include a paragraph IV certification to the '667 patent as well.

As required by statute and regulation, Apotex Inc. provided Pfizer with the requisite notice of its original paragraph IV ANDA filing, including the factual and legal basis for its certification. (Tao Decl. ¶ 22). In response, on December 17, 2008, Pfizer filed two actions—this action and an identical action in Illinois—against Apotex alleging infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A). (*See* D.I. 1, Compl.; Phillips Decl. Ex. A, NDIL Compl.). Apotex has answered and counterclaimed in Illinois, where the parties and the case are currently proceeding. (Phillips Decl. Ex. B, NDIL Answer; *see also id.* at Ex. Q, NDIL action March 24, 2009 Minute Entry regarding the initial status hearing status held that day). On March

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[5] All references to "Tao Decl." shall mean the Declaration of Bernice Tao, submitted concurrently herewith.

18, 2009, Apotex Inc. provided Pfizer with the requisite notice of its paragraph IV certification filing for the '667 patent; in response, Pfizer filed the First Amended Complaint in this action. (D.I. 25, First Am. Compl. ¶¶ 18, 52).

Pfizer did not file, and to this day has not filed, suit on the '104 patent, the '156 patent, or the '971 patent. The only named inventor on the '995 and '667 patents, Bruce D. Roth, is located in Ann Arbor, Michigan. (*See* D.I. 25 at Ex. A, '995 patent cover page; *id.* at Ex. B, '667 patent cover page). None of the Plaintiffs to this lawsuit have their main office in Delaware (D.I. 25, First Am. Compl. ¶¶ 5-9), and none of the Defendants have ***any*** offices in Delaware (Tao Decl. ¶¶ 8, 29).

In order to conserve the resources of the parties and this Court, and to avoid inconsistent results, Apotex inquired whether Pfizer would voluntary transfer and/or withdraw and dismiss this action in favor of the identical action pending in Illinois, where Apotex and Pfizer consented to proceed. Pfizer refused, thus necessitating this motion.

V. ARGUMENT

A. The Court Should Transfer This Action To The Northern District Of Illinois, Where An Identical Action Is Pending.

This Court has broad discretion to transfer "in the interest of justice . . . to any other district or division where it might have been brought." 28 U.S.C. § 1404(a); *see also Salovaara v. Jackson Nat'l Life Ins. Co.*, 246 F.3d 289, 297 n.5 (3d Cir. 2001) (citing *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995)). "The purpose of § 1404(a) is 'to prevent the waste of time, energy, and money and to protect litigants, witnesses, and the public against unnecessary inconvenience and expense.'" *Virgin Wireless, Inc. v. Virgin Enters. Ltd.*, 201 F. Supp. 2d 294, 299 (D. Del. 2002) (Robinson, C.J.) (quoting *Van Dusen v. Barrack*, 376 U.S. 612,

616 (1964)). The Court should consider "whether on balance the litigation would more conveniently proceed and the interests of justice be better served by transfer to a different forum." *Jumara,* 55 F.3d at 879 (citing 15 Charles Alan Wright et al., Federal Practice and Procedure § 3847 (2d ed. 1986)). In the end, the transfer inquiry is an "'individualized, case-by-case consideration of convenience and fairness.'" *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 29 (1988) (quoting *Van Dusen*, 376 U.S. at 622).

Here, of course, Pfizer not only could have brought this action elsewhere, ***but Pfizer, in fact, filed the exact same action against Apotex in the Northern District of Illinois***. In these circumstances, "[m]ost relevant to the courts [sic] inquiry is whether there are practical considerations that would make trial 'easy, expeditious, or inexpensive.'" *Brunswick Corp. v. Precor Inc.*, No. 00-691-GMS, 2000 WL 1876477, at *3 (D. Del. Dec. 12, 2000) (citing *Jumara*, 55 F.3d at 879). As this Court aptly explained in the context of a § 1404(a) motion when confronted with related litigation pending in another forum:

> If related cases are pending in the district to which transfer is sought, such fact weighs in favor of the transfer. *Affymetrix, Inc. v. Synteni, Inc.*, 28 F. Supp. 2d 192, 206 (D. Del. 1998). In a recent case granting a motion to transfer, the Court relied heavily on the existence of patent litigation in another forum involving "a parent patent of the one at issue" and a patent involving a similar type of product which was arguably "directly related" to the patent at issue. [*Brunswick*, 2000 WL 1876477, at *3 n.2].

Nilssen v. Osram Sylvania, Inc., No. 00-695-JJF, 2001 WL 34368395, at *4 (D. Del. May 1, 2001). Having concluded it would be a waste of judicial resources in requiring two different courts to construe and render *Markman* rulings on the same patents, this Court duly granted the motion to transfer. *See id.*; *Crackau v. Lucent Techs.*, No. 03-1376, 2003 WL 22927231, at *5 (D.N.J. Nov. 24, 2003) ("[T]he dispositive factor—as is often the case with transfer motions when a related case is pending in a different district—is the interest of all (parties, witnesses and

the court) in avoiding wasteful duplication of efforts.").[6]

Indeed, as other courts have acknowledged, "[b]ecause an identical case has been filed in another district, the central inquiry for the court is not—as it usually is in the context of motions to transfer—whether the case would be better litigated in one district or another," but rather "the sole question before the court is whether there exist adequate reasons for this action to be litigated twice . . . as opposed to only once." *Crackau*, 2003 WL 22927231, at *6. Having concluded there could be no legitimate reason for filing identical actions in two different courts, let alone litigating identical actions, courts have not hesitated to transfer. *See id.* at *6-8.

The same result is necessary here. Pfizer has no reason, much less a legitimate one, for proceeding with identical litigation here and in Illinois. The interest of justice weighs decidedly in favor of transfer in Illinois, where Pfizer voluntarily initiated suit.

1. The Interest Of Justice Mandates Transfer To The Northern District Of Illinois Where An Identical Action Is Pending.

"[I]t is in the interests of justice to permit suits involving the same parties and issues to proceed before one court." *Brunswick*, 2000 WL 1876477, at *3 (quoting *Liggett Group, Inc. v. R.J. Reynolds Tobacco Co.*, 102 F. Supp. 2d 518 (D.N.J. 2000)). Indeed, the Supreme Court has made clear that "[t]o permit a situation in which two cases involving precisely the same issues are simultaneously pending in different District Courts leads to the wastefulness of time, energy and money that [§] 1404(a) was designed to prevent." *Cont'l Grain Co. v. Barge FBL-585*, 364 U.S. 19, 26 (1960). "Where, as here, [a] related lawsuit[] [is] pending elsewhere, transferring a case serves not only private interests but also the interests of

[6] *See also Fairfax Dental (Ir.) Ltd. v. S.J. Filhol Ltd.*, 645 F. Supp. 89, 92 (E.D.N.Y. 1986) ("The pendency of a related case in the proposed transferee forum is a powerful reason to grant a motion for a change of venue." (quoting *Supco Auto. Parts, Inc. v. Triangle Auto Spring Co.*, 538 F. Supp. 1187, 1192 (E.D. Pa. 1982))).

justice because it eliminates the possibility of inconsistent results . . . and conserves judicial resources." *CIBC World Mkts., Inc. v. Deutsche Bank Sec., Inc.*, 309 F. Supp. 2d 637, 651 (D.N.J. 2004).

This Court frequently has heeded this admonition and transferred a case to another forum when a related action was pending. *Bayer Bioscience N.V. v. Monsanto Co.*, No. 03-023-GMS, 2003 WL 1565864, at *2 (D. Del. Mar. 25, 2003) (transferring action to district that had "on-going relationship" with the parties' disputes); *APV N. Am., Inc. v. Sig Simonazzi N. Am., Inc.*, 295 F. Supp. 2d 393, 399 (D. Del. 2002) (transferring action to forum where discovery in related litigation had already begun); *Nilssen*, 2001 WL 34368395, at *4; *Nilssen v. Everbrite, Inc.*, No. 00-189-JJF, 2001 WL 34368396, at *4 (D. Del. Feb. 16, 2001); *Affymetrix*, 28 F. Supp. 2d at 206 (acknowledging the importance of retaining related litigation in a single court, citing *Tracy v. Consol. Rail Corp.*, 723 F. Supp. 1051, 1052 (D. Del. 1989) and transferring action to forum where "all three" related cases "were pending before the same District Judge"). Further, in patent cases, the interest of justice, which includes judicial economy, may be determinative of a venue change even if the convenience of the parties and witnesses might call for a different result. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997); *see also*, *Doubletree Partners, L.P. v. Land Am. Am. Title Co.*, No. 3-08-cv-1547-O, 2008 WL 5119599, at *5-6 (N.D. Tex. Dec. 3, 2008) (concluding that the interests of justice "standing alone" warranted transfer despite the fact that the convenience of the parties and witness had not been demonstrated to favor transfer); Phillips Decl. Ex. M, *Abbott Labs. v. Teva Pharms. USA, Inc.*, No. 08-cv-1243 (N.D. Ill.) D.I. 41, Nov. 12, 2008 Mem. Op. at 13 (concluding "that the interests of justice strongly favor resolving all of the contested matters arising out of [defendant's] ANDA in one lawsuit", and transferring action to district where action involving

different patents and different plaintiffs—yet related technology—was pending); *Am. Tel. & Tel. Co. v. MCI Commc'n Corp.*, 736 F. Supp. 1294, 1309, 1313 (D.N.J. 1990) (transferring case where related action was pending despite the balance of private interest factors weighing against transfer).

This case is the poster-child for the needless and prejudicial duplicative litigation that § 1404(a) is designed to prevent. The same day Pfizer filed this action, Pfizer voluntarily filed an *identical* action against Apotex in Illinois. Apotex has already answered and counterclaimed in that action. That action will proceed no matter what happens here—thus, the question becomes, "[w]hy, under the circumstances, should there be two litigations where one will suffice?" *Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183 (1952). The answer is, there shouldn't be, not now, not ever—and for good reason. Allowing this case to proceed here will needlessly waste the resources of the parties and this Court, and seriously risk inconsistent results on the infringement and validity of the same patent. Transfer therefore is necessary to avoid needless duplication of effort; to conserve the resources of the parties and this Court; and to avoid the very real danger of inconsistent results.

Pfizer can muster no reason, and certainly not a legitimate one, for litigating this case twice in separate venues—or for trying to move forward in Delaware rather than in Illinois, or otherwise attempting to choose the judge and forum of its choice. Nor is Pfizer legally entitled to do so. The law requires that Pfizer's complaint be prosecuted in one jurisdiction. *See, e.g., Aventis*, 403 F. Supp. 2d at 489 ("[P]laintiffs may not file duplicative complaints in order to expand their legal rights.") (citation omitted). Even if Pfizer felt it needed to file a separate "protective" or "back-up" suit for jurisdictional purposes (it didn't, since Apotex previously identified an agent for service of process in Illinois just for this action), Pfizer may not prosecute

identical actions, especially after Apotex consented to suit in Illinois. That Pfizer has even attempted to do otherwise reeks of blatant forum-shopping. Such duplicative filings also violate Pfizer's statutory duty under the Hatch-Waxman Act to expedite this dispute, not prolong it with identical filings in separate districts. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

For these reasons alone, transfer to the Northern District of Illinois is appropriate and indeed required.

2. Courts Have Soundly Rejected Pfizer's Tactic Here Of Filing And Attempting To Maintain Related Actions In Different Districts.

This is not the first time that a court has been confronted with the same trick of filing identical actions against an ANDA-filer, with a view toward forum-shopping and/or outright delay. Other courts have expressly rejected such blatant forum-shopping. So, too, should this Court.

In a matter involving an ANDA for generic guaifenesin, the brand company (Adams), like Pfizer here, filed identical patent infringement actions against the ANDA-filer (Mutual) in both New Jersey and Pennsylvania. (*See* Phillips Decl. Ex. D, *Adams Respiratory Therapeutics, Inc. v. Pharm. Holdings Co.*, No. 2:06-cv-04700-HAA-ES (D.N.J. Nov. 16, 2006); Phillips Decl. Ex. E, *Adams Respiratory Therapeutics, Inc. v. Pharm. Holdings Corp.*, No. 2:06-cv-04418-PD (E.D. Pa. Nov. 2, 2006)). The ANDA-filer immediately answered and counterclaimed in Pennsylvania, and consented to proceed there. But the brand company objected. Having voluntarily sued in Pennsylvania, the brand company nonetheless said it would now rather proceed in New Jersey (just as Pfizer will likely say that, even though it voluntarily sued in Illinois, it would now rather proceed in Delaware). Under the guise of the so-called "first-filed" rule, the brand company moved to stay the Pennsylvania action that it voluntarily

filed, arguing that, after filing identical actions in separate venues, it somehow was now entitled to pursue its complaint in the jurisdiction, and before the judge, of its choice. On the same grounds, the brand company also had the temerity to ask the New Jersey court to enjoin the Pennsylvania court from proceeding with the action that the brand company itself had voluntarily initiated there.

Both courts saw right through the brand company's tactics, and properly denied the motions, rejecting the misuse of the first-filed rule and preventing blatant and improper forum-shopping. In denying the brand company's motion to enjoin the identical Pennsylvania action, the New Jersey court aptly explained:

> The "first-filed rule" is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient.
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> * * *
>
> While I am sympathetic to Adams' predicament, the situation is of its own making. If Adams wants to proceed in its first choice of forum, it knows how to unilaterally effectuate that circumstance.

(Phillips Decl. Ex. D, *Adams Respiratory Therapeutics, Inc. v. Pharm. Holdings Co.*, No. 2:06-cv-04700-HAA-ES (D.N.J. Nov. 16, 2006) D.I. 14, Nov. 16, 2006 Order at 2). The Pennsylvania court followed suit and denied the motion to stay, explaining:

> I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which Plaintiff almost exclusively relies – applies in the unique circumstances presented here . . . I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial. Accordingly, I will deny the Motion to Stay.

(Phillips Decl. Ex. E, *Adams Respiratory Therapeutics, Inc. v. Pharm. Holdings Corp.*, No. 2:06-cv-04418-PD (E.D. Pa. Nov. 2, 2006) D.I. 31, Nov. 2, 2006 Order at 2).

Other courts naturally have reached the same conclusion when confronted with this tactic in other ANDA cases. In *Aventis*, 403 F. Supp. 2d at 490, the brand company filed identical suits against the generic ANDA-filer in both Virginia and Maryland. The brand company then moved to stay the quicker Virginia case, instead preferring to proceed in the much slower Maryland forum. The brand company argued that the "first-filed" rule somehow entitled it to do so. The court disagreed, denying the brand company's motion to stay and holding that the first-filed rule does not apply where, as here, the "Plaintiffs filed the same case against the same Defendants in two different courts." *Aventis*, 403 F. Supp. 2d at 489. The court further confirmed that "plaintiffs may not file duplicative complaints in order to expand their legal rights." *Id.* (citations omitted).[7]

For much the same reasons, transfer is appropriate to discourage the gaming of the system that Pfizer has engaged in here.[8] This Court also should, and indeed must, reject any attempt by Pfizer to justify its duplicative filings under the first-filed rule. Pfizer is not entitled to

[7] The court also made clear that the first-filed rule applies in contexts not present here; namely: (1) when there is one patent involved but there are multiple defendants in different forums; or (2) when the defendant files its own "mirror image" infringement action against the plaintiff in another forum (typically after learning of the plaintiff's first-filed action). *See Aventis*, 403 F. Supp. 2d at 489. Neither scenario applies here. Further, as both this action and the identical Northern District of Illinois action were filed on the same day—December 17, 2008—Pfizer can not legitimately claim that this action is somehow earlier filed.

[8] Lest there be any doubt about Pfizer's true motives here, the Court's attention is drawn to the fact that Pfizer has previously litigated infringement and invalidity as to the '995 patent and obtained a favorable result in *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 525-26 (D. Del. 2005) (involving Ranbaxy's ANDA for generic atorvastatin calcium tablets), which was later reversed in part by the Federal Circuit in *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1286 (Fed. Cir. 2006).

file or maintain identical actions against Apotex in separate districts, under the first-filed rule or otherwise. And there is no right under the Federal Rules or otherwise to maintain so-called "protective actions," which, if anything, violate the spirit of the rules by proliferating duplication and wasting judicial and litigant resources.

3. Pfizer's Choice Of Illinois Should Control, And Its Duplicative Choice Of Delaware Should Be Accorded No Weight.

As an initial matter, Pfizer chose Illinois as an appropriate forum to litigate this dispute, having voluntarily sued Apotex there. Apotex agrees that Illinois is appropriate, and has consented to suit there. The plaintiffs' choice-of-forum inquiry should end there. Pfizer has argued in the District of Illinois action that Illinois was not its "real" or "first" choice and that Pfizer was somehow forced to file a so-called "protective" suit in Illinois. (Phillips Decl. Ex. O, NDIL action Mem. of Law in Support of Pls.' Mot. to Stay ("Pls. NDIL Stay Br.") at 2).[9] Such arguments are illusory. The fact is that Pfizer voluntarily chose Illinois. The reasons why are immaterial. That Pfizer also chose to sue here does not change the fact that Pfizer also chose to sue in Illinois, or otherwise diminish Pfizer's choice of Illinois. If anything, Illinois "is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie [there]." *Aventis*, 403 F. Supp. 2d at 490.

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[9] Indeed, Plaintiffs concede in their District of Illinois action stay briefing that this action and the Illinois action were filed ***within three hours of each other on the same day***. (Phillips Decl. Ex. O, Pls.' NDIL Stay Br. 4). Federal courts do not apply any "first filed" rule "mechanically" to actions filed close in time, or where the "first-filed" action is simply an attempt at forum shopping (as it is here, *see* footnote 8, *supra*). *Affinity Memory & Micro, Inc. v. K & Q Enters., Inc.*, 20 F. Supp. 2d 948, 954-55 (E.D. Va. 1998) (rejecting first-filed rule when second action was filed only two weeks after the first); *Employers Reinsurance Corp. v. MSK Ins., Ltd.*, No. 01-2608-cm, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003) (refusing to apply rule when actions were filed eleven weeks apart). Pfizer filed this action ***nearly simultaneously*** with the filing of the District of Illinois action. As one Court has stated, "application of the first-filed rule in this case seems unwarranted where the second action was filed only two weeks after the first action ...." *Affinity Memory*, 20 F. Supp. 2d at 955.

To borrow from the Pennsylvania court in *Adams Respiratory*, "Plaintiff has chosen to sue [in Illinois]; it can not credibly complain that proceeding with [that] suit is prejudicial." (Phillips Decl. Ex. E, *Adams Respiratory Therapeutics, Inc. v. Pharm. Holdings Corp. et al.*, No. 06-4418-PD (E.D. Pa. Nov. 2, 2006) D.I. 31, Nov. 2, 2006 Order at 2). "[I]t would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed . . . ." (*Id.*) The Court, therefore, should hold Pfizer accountable and defer to the forum (Illinois) that Pfizer freely and voluntarily chose. *See Jumara*, 55 F.3d at 880 (holding that while courts might defer to a plaintiff's choice of forum, such deference is inappropriate where the plaintiff has freely chosen another forum, such as through a choice of venue agreement).

The Court, moreover, should accord no weight to Pfizer's choice of Delaware for this duplicative action. First, it is well settled in this District that any deference that might be owed to a plaintiff's choice of forum is limited by the "strong policy favoring the litigation of related claims before the same tribunal." *Smithkline Corp. v. Sterling Drug, Inc.*, 406 F. Supp. 52, 54-56 (D. Del. 1975) (holding that the substantial weight accorded to a plaintiff's choice of forum was overridden by the benefit of avoiding duplicative litigation); *see also Ballard Med. Prods. v. Concord Labs., Inc.*, 700 F. Supp. 796, 801-02 (D. Del. 1988) (holding that the interests of justice were better served by transfer to forum where action involving "almost identical issues" was pending); *Bristol-Myers Squibb Co. v. Andrx Pharms., LLC*, No. 03-2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (holding that plaintiff's "double-filing" of identical actions in ANDA patent infringement matter "does cut against its choice" of forum); *Crackau,* 2003 WL 22927231, at *6 (holding that any deference is offset by the costs of duplicative litigation).

Second, "[w]hen the central facts of a lawsuit occur outside the forum state, a plaintiff's selection of that forum is entitled to less deference." *Ricoh Co. v. Honeywell, Inc.*, 817 F. Supp. 473, 481 (D.N.J. 1993). "In a patent infringement action, the locus of operative facts is the jurisdiction where the design and development of the infringing patent [sic] [product] occurred." *Bristol-Myers*, 2003 WL 22888804, at *3; *see also Ricoh*, 817 F. Supp. at 481 n. 17 (holding that "[i]n patent infringement actions, as a general rule, the preferred forum is that which is the *center of gravity* of the accused activity[,]" which is typically "the location of a product's development, testing, research and production.") (emphasis in original); *Virgin Wireless*, 201 F. Supp. 2d at 300 ("center of operative facts in the action" favored transfer out of Delaware); *Brunswick*, 2000 WL 1876477, at *2 ("[T]he plaintiff's preference for Delaware is not given as much deference because most of the events at issue, that is, the design and manufacture of the exercise equipment, occurred outside of Delaware"); *Affymetrix*, 28 F. Supp. 2d at 199 ("[T]he weaker the connection between the forum and *either* the plaintiff *or* the lawsuit, the greater the ability of a defendant to show sufficient inconvenience to warrant transfer.") (emphasis in original); *Shatterproof Glass Corp. v. Guardian Indus. Corp.*, No. 86-607-CMW, 1987 WL 11773, at *3 (D. Del. 1987) (transferring action to district where defendant "allegedly infringed the patent").

Here, of course, the ANDA filing and accused product that forms the basis of this dispute has no connection to Delaware—and Pfizer cannot argue otherwise.[10] Moreover, nothing

[10] Pfizer has argued in its Northern District of Illinois stay briefing that Apotex's alleged patent infringement is a tort that injured Pfizer in Delaware (Phillips Decl. Ex. O, Pls.' NDIL Stay Br. 14-15)—but this argument defies logic. "In a patent infringement action, the locus of operative facts is the jurisdiction where the design and development of the infringing patent [sic] [product] occurred." *Bristol-Myers Squibb Co.*, 2003 WL 22888804, at *3; *see also Ricoh,* 817 F. Supp. at 482 n.17. This Court should reject any Pfizer argument that somehow courtesy copies of Apotex

of relevance concerning the subject matter of the '995 and '667 patents occurred here either. Indeed, the only named inventor—Bruce D. Roth—is, according to the face of those patents, located in Michigan, not Delaware. Further still, none of the Plaintiffs to this lawsuit have their main office in Delaware (D.I. 25, First Am. Compl. ¶¶ 5-9), and none of the Defendants have ***any*** offices in Delaware (Tao Decl. ¶¶ 8, 29). The only relation this suit appears to have to this forum is that a few of the parties happen to be incorporated in Delaware—but the case law is clear that such a minimal connection to Delaware is insufficient to defeat transfer. *APV*, 295 F. Supp. 2d at 398-400 (holding incorporation of both plaintiff and defendant in Delaware "not dispositive" and ordering transfer); *Nilssen*, 2001 WL 34368395, at *2 (minor sales and minimal presence of sales personnel are insufficient to defeat transfer, despite Delaware incorporation); *Bayer Bioscience*, 2003 WL 1565864, at *2 (transferring action where "no party maintains operations in Delaware," though one was a Delaware entity).

Accordingly, Pfizer's choice of Illinois should control and its duplicative choice of Delaware, which has no connection to the actual subject matter of this suit, should be accorded no weight. (Phillips Decl. Ex. M, *Abbott Labs v. Teva Pharms. USA, Inc.*, No. 08-cv-1243 (N.D. Ill.) D.I. 41, Nov. 12, 2008 Mem. Op. at 6, 13 (transferring action where, although suit was filed in a forum that was home to one of the Plaintiffs (Abbott Labs.), the court felt that Plaintiffs had only "an attenuated interest in proceeding in [the Northern District of Illinois],

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Inc.'s paragraph IV certification notice letters to Pfizer litigation counsel in Delaware establish a sufficient connection between this case and Delaware sufficient to maintain this action here. To the extent that the destination of Apotex Inc.'s notice letters plays any role in a "locus of operative facts" analysis, the statute giving rise to Pfizer's patent infringement claim mandates only that notice be given to the patent owner(s) and NDA-holder (21 U.S.C. § 355(j)(2)(B)(iii))—these entities were all served in New York, New Jersey, Michigan and Ireland. (D.I. 25, First Am. Compl. ¶¶ 5-9; Tao Decl. Ex. A, Apotex Inc.'s 11/4/08 Notice Letter at 1; Phillips Decl. Ex. S, Apotex Inc.'s March 18, 2009 Notice Letter at 1).

where none of the material events giving rise to [the] lawsuit [, such as ANDA preparation and development work underlying the application,] occurred....")).

B. In The Alternative, The Court Should Stay These Proceedings Pending Resolution Of The Identical Proceeding In The Northern District Of Illinois.

In the alternative, Apotex respectfully requests that the Court stay the proceedings in this District. "[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). Courts routinely stay an action when a related action is pending in another court. *See* 17A Charles Alan Wright et al., Federal Practice and Procedure § 4247 (3d ed. 1998) ("[I]t is well settled that if the same issues are presented in an action pending in another federal court, one of these courts may stay the action before it . . . ."); *Monsanto Co. v. Aventis Cropscience SA*, No. 00-1013-SLR, 2001 WL 640969, at *5 (D. Del. May 16, 2001) (staying action pending resolution of a related proceeding).

Absent dismissal or a transfer, the existence of the identical action in Illinois alone is reason enough to stay these proceedings. Otherwise, there is a serious risk of inconsistent rulings on the infringement and validity of the patents-in-suit. Moreover, the Court should not permit Pfizer to prejudice Apotex, as well as waste the resources of this Court, by pursuing duplicative proceedings. Nor would a stay prejudice Pfizer in the least, since it freely chose Illinois, where Apotex consented to suit and the action is proceeding.

VI. CONCLUSION

This case does not belong here. It belongs in the Northern District of Illinois, where an ***identical*** action is already pending involving the same parties, patents and accused product. The parties there have consented to jurisdiction and venue and are at issue. The Court should reject Pfizer's blatant attempt at forum-shopping, just as this Court and others hearing ANDA cases have previously done, and transfer this case to the Northern District of Illinois. In the alternative, the case should be stayed pending resolution of the identical Illinois action.

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Respectfully submitted,

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